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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
[illegible]	04/27/2000	Rajesh Ranganathan	[illegible] 521002	1966

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EXAMINER
WOITACH, JOSEPH T

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/559,622	Applicant(s) Ranganathan et al.
	Examiner Joseph Woitach	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Dec 2, 2002*.

2a) [X] This action is **FINAL**. 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-25, 27, 28, and 30-33* is/are pending in the application.

4a) Of the above, claim(s) *1-8, 10, and 12-19* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *9, 11, 20-23, 27, 28, 32, and 33* is/are rejected.

7) [X] Claim(s) *24, 25, 30, and 31* is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s). ___
4) [ ] Interview Summary (PTO-413) Paper No(s). ___
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other: ___

DETAILED ACTION

This application filed April 27, 2000, claims benefit to provisional application 60/131,149, filed April 27, 1999.

Applicants' amendment filed December 2, 2002, paper number 18, has been received and entered. Claims 26 and 29 have been canceled. Claims 9, 11 and 20-23 have been amended. Claims 30-33 have been added. Claims 1-25, 27, 28, 30-33 are pending.

Election/Restriction

Applicant's election without traverse of group V, claims 9 , 11, 20 and 21 in Paper No. 11 is acknowledged. Additionally, newly added claims 30-33 are dependent on claims 22 and 23, and are drawn to the elected invention. Claims 1-8, 10 and 12-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 9, 11 and 20-25, 27, 28 and 30-33 are currently under examination.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claims 22 and 23 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

Amendments to the claims has obviated the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, 22 and 23 stand rejected and newly amended claims 20, 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous office action and below.

Applicants summarize the basis of the rejection and note the amendments to the claims. In traverse of the rejection Applicants argue that all the claimed subject matter need not be completely described, and that the specification needs to provide a clear description allowing the ordinary artisan to recognize that he or she invented what is claimed, citing several court decisions and the MPEP in support of their argument (page 9-10). Discussing *Lilly* and *Vas-Cath*, Applicants argue that they have met the standards set forth in these decisions because the specification would indicate to one of ordinary skill in the art that a family of functional serotonin-gated anion channels have been discovered. Noting that only one form of MOD-1 is specifically identified in the specification, Applicants argue that the specification provides adequate description of more than a single gene wherein the single disclosed sequence would be representative of any functional serotonin which would hybridize to this sequence (pages 11-13). Finally, pointing to Example 9 in the Written Description Guidelines, Applicants argue that the present facts fall squarely within the fact pattern of sequences which specifically hybridize under stringent conditions (pages 13-15). See Applicants' amendment, pages 9-15. Applicants' arguments have been fully considered, but not found persuasive.

First, it is noted that claims 9, 11, 20 and 21 recite hybridization conditions which the specification defines as 'lower stringency conditions' (page 34, lines 1-11), and arguments that these claims fall within Example 9 in the written description guidelines are not persuasive because clearly these claims do not encompass stringent hybridization conditions. With respect to claims 22 and 23, it is noted that these claims do recite conditions considered 'stringent',

however based on the evidence of record it appears that these claims also fall outside the fact pattern of the Examples. Specifically, the Example is based on the ability to identify other sequences in nature which are highly homologous, and because they are found in nature would likely encode a protein with similar amino acid composition and thus function. However, a comparison of identified serotonin-gated anion channel sequences from other species indicate sufficient amino acid sequence differences wherein the polynucleotide sequences encoding the serotonin-gated anion channel would not be identified by SEQ ID NO:2 (see for example Blakely et al. figure 4 or Sze *et al.* Nature, 403:560-564, Figure 1). Thus, the specific conditions and sequences would not identify other related functional family members present in nature which are functionally the same. Applicants' arguments that the claims fall within the fact pattern of Examples presented in the written description guidelines is not persuasive because the specific facts in the present disclosure are not directly comparable to those set forth in the hypothetical examples because related species would not be identified with the single disclosed SEQ ID NO: 2.

With respect to other species of polynucleotides encoding a functional serotonin-gated anion channel encompassed by the claim, it is noted that the single disclosed polynucleotide set forth in SEQ ID NO: 2 could be modified wherein sufficiently few alterations are introduced such that the sequence would hybridize to SEQ ID NO: 2. Importantly, the specification is silent with respect to specific sequences which can and can not be modified such that a functional serotonin-gated anion channel would be produced. For example, presented with two sequences,

SEQ ID NO: 2 and a derivative of this sequences wherein modifications are introduced, the artisan would not be able to determine whether the second sequence would encode a functional serotonin-gated anion channel like SEQ ID NO: 2. The specification provides only one species of a enormous genus of sequence which hybridize and a potentially large genus of sequences which encode a functional serotonin-gated anion channel. As noted in the previous office action, the only variants of SEQ ID NO: 2 which would hybridize that are specifically disclosed are sequences which encode a channel protein which lacks the activity which would be assayed in the instantly claimed methods. Examiner agrees that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention (Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991)) and would concede that one could test any sequence which would hybridize to SEQ ID NO: 2 under any condition, however as noted in the previous office action adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). With respect to *Lilly* it was stated:

A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals

appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

In the instant case, providing specific conditions for identifying structurally similar polynucleotides by hybridization and merely excluding non-functional sequences from all the sequences which would hybridize does not provide adequate written description of the specific polynucleotides which encodes a functional serotonin-gated anion channel.

The current case is more analogous to that in *Ex parte Maizel.* It was found in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA segment known to the inventor. Clearly the disclosure is not commensurate in scope with the claims."

Similarly, the instant claims require a functional serotonin-gated anion channel however the art of record indicates that such sequences do not exist in nature, and the specification only provides at most a means for identifying sequences that fall within the scope of the functional language of the claim by actively testing each individual sequence which would hybridize. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. With respect to the citation presented in *Martin*

v. Mayer, Examiner agrees that which is conventional in the art need not be disclosed, however the genus of sequences encompassed by the claims are not supported by the art of record nor are potential methods for generating such sequences conventional. Furthermore, as noted in *Martin v. Mayer,* and more to point in the instant case, 'It is not "a question of whether on skilled in the art might be able to construct the patentee's device from the teachings of the disclosure....Rather, it is a question of whether the application necessarily discloses that particular device' (page 1337, citing *Jepson v. Coleman*). Similar to the conclusion of the Board, in the instant case, the present specification fails to satisfy the requirements of 35 USC 112, first paragraph.

Therefore, only SEQ ID NO: 2 meet the written description provision of 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11, 22 and 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to the claims has obviated the basis of each of the specific rejections.

Claims 11, 23, 27, 28, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Specifically, claims 11 and 23 have been amended to recite that a purified serotonin-gated anion channel is used to characterize a drug by measuring current flux through the channel, however this is not possible with a purified channel. The ability of measuring a current flux is dependent on generating a disequilibrium of ions on either side of the channel such as in the context of a cell, which can not be done with a purified protein. More clearly indicating the conditions of how the current flux is measured on a purified protein would obviate the basis of the rejection. Dependent claims 27 and 28, and newly added claims 32 and 33 are included in the basis of the rejection because they fail to clarify the basis of the rejection only indicating the type of current flux which is measured.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 11 rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Scrogin *et al.* (IDS ref. Am. J. Physiol, Dec 1998) is withdrawn.

Claims 9 and 11 rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Ali *et al.* (IDS reference J. Physiol. May 1998) is withdrawn.

Claims 9 and 11 rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Montigny *et al.* (IDS reference Science, 1978) is withdrawn.

Claims 9 and 11 rejected and newly added claims 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Garner *et al.* (IDS reference Eur. J. Pharm., 1993) is withdrawn.

Claims 20 and 21 rejected under 35 U.S.C. 102(a) as being anticipated by Hamdan *et al.* (J Neuro, April 1999) is withdrawn.

Claims 9, 11 and 20-29 rejected under 35 U.S.C. 102(b) as being anticipated by Horvitz *et al.* (Science May 1982) is withdrawn.

Amendments to the claims have differentiated the claimed invention from that disclosed in each of the above references. Specifically, claims 9, 20-29 now encompass the method step of contacting the cell or generating a transgenic nematode with a first purified polynucleotide which is not taught or suggested by any of the above references. Additionally, claims 11 and 23 now directed to using a purified serotonin receptor protein in the assay method. In each of the references the activity of a serotonin gated receptor is assayed, however it is an endogenously expressed receptor, not one produced by a heterologous polynucleotide. Further, the assay is

performed in the context of a cell or animal model and not with a purified protein as required in claims 11 and 23.

Conclusion

No claim is allowed. The claims are free of the art of record because the art fails to teach the specific methods instantly claimed. Claims 24, 25, 30 and 31 are objected for being dependent on rejected claims. At the time of filing serotonin-gated anion channels were known in the art, however the specific sequence set forth in SEQ ID NO: 2 was not described, therefore the use of said sequence for obtaining other related sequences would not be anticipated or obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1632